K082519

SEP 2 6 2008

SECTION II. 510(K) SUMMARY

A. DEVICE NAME

Proprietary Name:	FINECROSS™ MG Coronary Micro-Guide catheter
Classification Name:	Catheter, Continuous Flush
Common Name:	Micro-Guide Catheter

B. PREDICATE DEVICE

The predicate devices are the Rapidtransit and Tornus, which are manufactured by Cordis Neurovascular Inc. and Asahi Intecc Co LTD, respectfully. The predicate devices have been cleared through the premarket notification process, Rapidtransit K972518 and Tornus K051772.

C. INTENDED USE

The product (Finecross™ MG) is intended to be percutaneously introduced into blood vessels and support a guide wire while performing PCI (percutaneous coronary intervention). The product is also intended for injection of radiopaque contrast media for the purpose of angiography.

D. DESCRIPTION

FINECROSS MG consists of a catheter shaft, a hub and an anti-kink protector. The catheter shaft has reinforcing braided mesh, thus achieving the high shaft strength and anti-kink characteristics. The shaft has gradual hardness change from the proximal to the distal portion. This is achieved by joining outer layers of material with different hardness. By using polytetrafluoroethylene (PTFE) as the inner layer, high inner face mobility has been achieved. The outer surface of the catheter is coated with a hydrophilic polymer; therefore, it demonstrates a high lubricity upon moistening.

E. PRINCIPLE OF OPERATION / TECHNOLOGY

The FINECROSS™ MG Coronary Micro-Guide catheter is operated manually or by a manual process.

F. DESIGN / MATERIALS

The FINECROSS™ MG Coronary Micro-Guide catheter uses similar materials as the predicate devices. Differences in materials between the devices do not raise any new issues of safety and effectiveness.

G. SPECIFICATIONS

Usable length of catheter:	1300 and 1500mm
Outer diameter of catheter (distal end):	1.8Fr (0.60mm)
Outer diameter of catheter (proximal end):	2.6Fr (0.870mm)
Inner diameter of catheter:	0.018" (0.45mm) to 0.0221" (0.55mm)
Radiopaque markers:	1

H. PERFORMANCE

The performance of the FINECROSS™ MG Coronary Micro-Guide catheter is substantially equivalent to the performance of the predicate devices. The equivalence was shown through bench testing.

I. ADDITIONAL SAFETY INFORMATION

Sterilization conditions have been validated in accordance with EN ISO 11135-1 "Sterilization of health care products – Ethylene Oxide – Part 1: requirements for development, validation and routine control of sterilization process for medical devices." to provide a Sterility Assurance Level of 10^{-6}.

Blood contacting materials were tested in accordance with the test recommendations in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part I: Evaluation and Testing." The FINECROSS™ MG Coronary Micro-Guide catheter is categorized as "Externally Communicating Device, Circulating Blood, Limited Contact (≤24hrs)". The blood contacting materials were found to be biocompatible.

Expiration dating for the FINECROSS™ MG Coronary Micro-Guide catheter will be 2 years.

J. SUBSTANTIAL EQUIVALENCE

The FINECROSS™ MG Coronary Micro-Guide catheter submitted in this 510(k) is substantially equivalent[1] in intended use, design, principle of operation / technology, materials and performance to the Rapidtransit and Tornus, which are manufactured by Cordis Neurovascular Inc. and Asahi Intecc Co LTD, respectfully. Differences between the devices do not raise any issues of safety or effectiveness.

[1] A statement of substantially equivalence to another product is required by 21CFR807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977)

K. SUBMITTER INFORMATION

Name and Address

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Contact Person

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Date Prepared

August 6, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

Terumo Medical Corporation
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K082519
FINEVROSS MG Coronary Micro-Guide Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Catheter Continuous Flush
Regulatory Class: Class II
Product Code: KRA
Dated: September 23, 2008
Received: September 24, 2008

Dear Mr. Job:

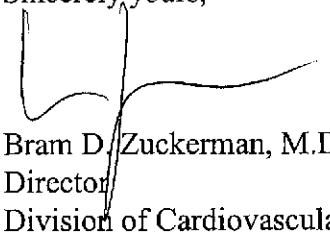
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082519

Device Name: FINECROSS™ MG Coronary Micro-Guide catheter

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082519